DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 5, 2014

Medtronic Sofamor Danek USA Inc.
Ms. Courtney N. Long
Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K141824
Trade/Device Name: MASTERGRAFT® Matrix EXT
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: July 1, 2014
Received: July 7, 2014

Dear Ms. Long:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Laurence D. Coyne -A

For Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141824

Device Name
MASTERGRAFT® Matrix EXT

Indications for Use *(Describe)*

MASTERGRAFT® Matrix EXT is to be combined with autogenous bone marrow and is indicated for bony voids or gaps that are not intrinsic to the stability of the bony structure and can be used as a bone graft extender.
The device is to be gently packed into bony voids or gaps of the skeletal system (i.e., the posterolateral spine, pelvis, ilium, and/or extremities). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The device resorbs and is replaced with bone during the healing process.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(K) Summary

I. SUBMITTER NAME & ADDRESSS:

Medtronic Sofamor Danek USA, Inc
1800 Pyramid Place
Memphis, Tennessee 38132
Telephone: (901) 396-3133
Fax: (901) 346-9738
Establishment Registration: 1030489

CONTACT PERSON: Courtney N. Long
Regulatory Affairs Specialist

DATE PREPARED: July 1, 2014

II. PROPOSED PROPRIETARY TRADE NAME: MASTERGRAFT® Matrix EXT

DEVICE CLASSIFICATION NAME: Resorbable Calcium Salt Bone Void Filler

REGULATION NUMBER: 21 CFR 888.3045

CLASSIFICATION PRODUCT CODE: MQV

CLASS: II

III. IDENTIFICATION OF LEGALLY MARKETED DEVICES:

TABLE 1. Legally Marketed Devices

Device Name	510(k)	Substantial Equivalence Date
MASTERGRAFT® UltraMatrix	K130335	04/19/2013
MASTERGRAFT® Strip and MASTERGRAFT® Putty	K140375	04/18/2014

IV. DEVICE DESCRIPTION:

MASTERGRAFT® Matrix EXT is made from a combination of medical grade purified collagen of bovine origin and biphasic calcium phosphate ceramic. In the devices, the collagen is a highly purified (>95%) Type I bioresorbable lyophilized collagen. The biphasic ceramic portion of the

device is provided in a 15 percent hydroxyapatite and 85 percent β-tricalcium phosphate formulation.

MASTERGRAFT® Matrix EXT is supplied sterile in a premixed strip form for single patient use.

The device is a biocompatible, osteoconductive, porous implant that allows for bony ingrowth across the graft site while resorbing at a rate consistent with bone healing. The device readily absorbs bone marrow aspirate.

The purpose of this Traditional 510(k) application is the addition of a new contraindication to the Instructions for Use (IFU) for MASTERGRAFT® Matrix EXT.

V. INDICATIONS FOR USE:

MASTERGRAFT® Matrix EXT is to be combined with autogenous bone marrow and is indicated for bony voids or gaps not intrinsic to the stability of the bony structure and can be used as a bone graft extender.

The device is to be gently packed into bony voids or gaps of the skeletal system (i.e., the posterolateral spine, pelvis, ilium, and/or extremities). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The device resorbs and is replaced with bone during the healing process.

VI. SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS:

Comparison Feature	**Subject MASTERGRAFT® Matrix EXT**	**Predicate MASTERGRAFT® UltraMatrix**
Indication for Use	Identical	K130335 (S.E. 04/19/2013)
Fundamental Scientific Technology • Operating Principle • Mechanism of Action	Identical	K130335 (S.E. 04/19/2013)
Basic Design	Identical	K130335 (S.E. 04/19/2013)
Performance	Identical	K130335 (S.E. 04/19/2013)
Manufacturing principles	Identical	K130335 (S.E. 04/19/2013)

Comparison Feature	Subject MASTERGRAFT® Matrix EXT	Predicate MASTERGRAFT® UltraMatrix
Sterilization	Identical	K130335 (S.E. 04/19/2013)
Shelf-Life	Identical	K130335 (S.E. 04/19/2013)
Packaging	Identical	K130335 (S.E. 04/19/2013)
Material Composition • Collagen • Granules	Identical	K130335 (S.E. 04/19/2013)
Use of rigid fixation	Identical	K130335 (S.E. 04/19/2013)
Safety and Effectiveness profile	Identical	K130335 (S.E. 04/19/2013)

VII. DISCUSSION OF NON-CLINICAL TESTING:

Non-clinical testing was performed in support of substantial equivalence for MASTERGRAFT® Strip cleared under K082166 (S.E. 06/02/2009). This data is considered relevant to and supportive of the cited predicate K130335 (S.E. 04/19/2013).

The non-clinical testing was conducted in accordance with FDA Recognized Consensus Standards and FDA Guidelines, where applicable. No new non-clinical testing was performed or submitted in support of this 510(k) application.

VIII. CONCLUSION:

Documentation provided in this submission demonstrates that the subject device is substantially equivalent to the previously cleared bone void filler MASTERGRAFT® UltraMatrix (K130335, SE 04/19/2013) and MASTERGRAFT® Strip and MASTERGRAFT® Putty K140375 (S.E. 04/18/2014).

The subject device is substantially equivalent to predicate MASTERGRAFT® UltraMatrix K130335 (04/19/2013) in several categories including: indication, material composition (including biphasic calcium phosphate granules and collagen), biodegradability, sterility, shelf-life, need for rigid fixation, biocompatibility and the ability to resorb during the healing process. The subject device is also substantially equivalent to K140375 (S.E. 04/18/2014) MASTERGRAFT® Strip and MASTERGRAFT® Putty related to the additional contraindication identified in the labeling.